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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,658	01/24/2002	Hiromi Nambu	218360US0	9726
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C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,658

Applicant(s)

NAMBU ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5, 7, 8, 10-22, 29-36 and new claims 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5, 7, 8, 10-22, 29-36 and new claims 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration, amendment and remarks, all filed 8/31/06. New claims 37-42 are added. Claims 1, 3-5, 7, 8, 10-22, 29-36 and new claims 37-42 are pending.

Response to Arguments

Rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 29, 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

In the instant case, applicant has not provided a description of the structure or a representative number of compounds or a description of the chemical derived from modifying polyvinyl alcohol with itaconic acid, sulfonic acid and maleic acid. The specification has not provided description of how to obtain a representative chemical compound derived from

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modifying polyvinyl alcohol with itaconic acid, sulfonic acid and maleic acid. In other words, the Applicant has not described with sufficient clarity compounds that are obtained as a result of modifying polyvinyl alcohol with itaconic acid, sulfonic acid and maleic acid. The specification fails to provide how to make the modified polyvinyl alcohol from itaconic acid, sulfonic acid and maleic acid and the polyvinyl alcohol.

The specification has not provided guidance as to what compound is produced from polyvinyl alcohol as a result of the modification with itaconic acid, sulfonic acid and maleic acid.

Paragraph 39 of the instant specification, mentions itaconic acid, sulfonic acid and maleic acid modified polyvinyl alcohol without providing what the modified polyvinyl alcohol may be. In the chemical science, compound A may react with compound B to produce more than one compound depending on the reaction conditions and even then, the probable reaction products may be mentioned, specifically indicating the conditions that form what product. For example, Funes in the J. Agric. Food Chem. Describes effects of reaction conditions and reactant concentrations on polymerization of lysozyme reacted with peroxidizing lipids (Funes et al. "Effects of Reaction Conditions and Reactant Concentrations on Polymerization of Lysozyme Reacted with Peroxidizing Lipids," in the J. Agric. Food Chem.. 1982, 30, 1204-1208).

4. Claims 35 and 40 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection

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The as filed specification does not support a gel having viscosity in the range of 300,000 to 20,000,000 mPa.s. The specification supports provides support for gel having viscosity of 100,000 to 20,000,000 mPa.s in paragraph [0104] of the published application.

The as filed specification does not support a method that excludes a heat/warming step, see paragraphs [0112] to [0116], there is no disclosure that heat is excluded.

This rejection may be overcome by removing the new matter from the claims.

5. Claims 1, 3-5, 7, 8, 10-22, 30-36 and 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a “viscosity of 300,000 mPa.s or more.” The meets and bounds of “more” is not defined. Specifically, “more” is relative term that includes any viscosity amount that is well greater than 300,000 and even up to infinity if there the upper end of the viscosity may be governed by infinity. Specifically, applicant’s specification limits the viscosity to be at a maximum of 20,000,000 mPa.s, with preferred limit of 15,000,000 mPa.s, particularly 10,000,000 mPa.s and a gel having a viscosity in the range of 100,000-20,000,000 is moldable into a sheet (paragraph [0104]). There is thus a viscosity limit for the gel. Thus, claim 1 has not provided the meets and bounds of the viscosity.

6. Claims 37-39 do not provide the structure of the polyvinyl alcohol after modification with itaconic acid, sulfonic acid and maleic acid and it is unclear what chemical compound is formed structurally and chemically.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-5, 7, 8 and 10-22, 29-36 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hori et al. (US 4,830,633).

Hori discloses depilatory composition comprising film forming polymer, depilatory medicine and additives such as alkali agent, hair swelling accelerating agent, a filler, perfume and coloring agent (column 2, lines 3-10). The film forming polymer is selected from the group of polyvinylpyrrolidone, polyacrylamide, polyacrylic acid and salts thereof, polyvinyl alcohol, carboxymethyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, gelatin, alginic acid, alginic acid salts, polyethylene glycol, gum arabic, acrylic esters and polyvinyl methyl ether in an amount of 1-70 wt%, 3-20 wt% depilatory medicine selected from the group of thioglycolic acid or its salts; water; 0.1-5 wt% alkali agents selected from the group of ammonium salt, metal salt of organic dicarboxylic acid, potassium hydroxide, calcium hydroxide and sodium hydroxide; urea as hair swelling accelerating agent; glycerin; dactyl phthalate plasticizer; an silicon dioxide or calcium carbonate or clay or kaolin or aluminum hydroxide (column 2, line 11 to column 3 line 55 and examples 1, 2 and 7 and claims 1, 3, 5, 6, and 8-10). The composition has a viscosity of from 0.1 to 1,000 poise at 30 °C (column 2, line 53). The composition is applied to underarm and allowed to stand for 15 minutes (example 7)

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and 10 minutes (example 9) and 8 minutes (example 10). Since Hori teaches the same amount of cross-linking agent (calcium hydroxide) and same amounts of hydrophilic polymer as in the instant claim, it is inherent that the depilatory composition of the prior art, Hori would have the same equivalents of cross-linking agent to ionic group of the hydrophilic polymer as recited in instant claim 19. The process of instant claim 20 applies the composition to an area that requires depilation and the process disclosed in Hori meets that limitation. Hori further discloses homo- or and copolymers of acrylic acid or methacrylic acid esters in claim 4. The polymers of Hori meet the limitations of the polymers in claims 14-16; calcium hydroxide (Example 6) meets claim 17. Regarding claim 22, it is noted that hair grows on the faces of animal subjects and is one of the obvious areas whose unwanted hair is depilated. Non-woven fabrics, paper, cloth, and foamed sheets serve as support material for the gel (column 4, lines 22-30), the gel support of the sheet is heated after application on the area needing depilation (column 4, lines 53-59); the gel is peeled off (column 4, lines 8-19) meeting the method claims 20, 36.

Claims 41 and 42 direct the support to be non-moisture-permeable and sparingly moisture permeable respectively and it flows from these limitations recited in these claims that the moisture permeability of the support provides no unusual properties or functions or unexpected results to the gel composition and thus provides that moisture permeable support or sparingly moisture permeable support or non-moisture-permeable support does not provide unexpected results to the depilatory gel composition. In the instant case, Hori's supported gel composition provides the same effect as the instant composition.

Therefore, Hori discloses that a sheet material made of plastic film or paper, non-woven fabric and cloth having a thickness of about 5 to 100 μm (column 3, lines 50-56), hydrophilic

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non-woven fabric, foamed sheets (column 4, lines 22-31), (meth)acrylonitrile and maleic anhydride graft (column 4, lines 41-68) can be placed over the film or coated with the film for removing hair without leaving residue. Therefore, Hori contemplates the use of a sheet having the composition of the type taught by the instant claims.

Hori differs from the instant claim in the viscosity of the Hori gel is from 0.1 to 1,000 poise at 30 °C (column 2, line 53), which is from 10 mPa.s to 100,000 mPa.s or a preferred viscosity of 0.2 to 100 poise (20 mPa.s to 10,000 mPa.s), while the claimed viscosity is 300,000 mPa.s. Hori contemplates a 10,000 fold increase from going from 10 mPa.s to 100,000 mPa.s or 500 fold increase from going from 20 mPa.s to 10,000 mPa.s for the preferred range. Further, the claimed viscosity is three times the viscosity of the Hori gel at the upper end. Gleaning from applicant's specification, a range of viscosity from 100,000 to 20,000,000 mPa.s (page 7, right column, lines 4 and 5 of the published application) is contemplated, which is a 200 fold from going from 100,000 to 20,000,000 mPa.s. There is no demonstration that a specific viscosity of the gel composition provides unusual/unexpected result to the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the gel formulation of Hori, having a viscosity in the range of 10 mPa.s to 100,000 mPa.s in the method of Hori to remove hair. One having ordinary skill in the art would have been motivated to use a gel formulation to remove hair where the gel composition has a viscosity that is 10,000 or 500 fold the viscosity of the Hori gel at about between 100,000 and 1,000,000,000 mPa.s or 10,000 to 5,000,000 mPa.s preferred, with the expectation that the gel would effectively remove hair. The upper limits of the general range and the preferred range are greater than the recited 300,000 mPa.s as in claim 1 and 5,000,000 lies within the range

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recited in claim 40. In the absence of factual evidence, a gel having a viscosity of 300,000 mPa.s is not inventive over a gel having a viscosity of 100,000 mPa.s and which may be increased 500 or 10,000 fold.

Response to Argument

9. Applicant's arguments filed 8/31/06 have been fully considered but they are not persuasive.

a) Applicants argue that Hori discloses a fixed viscosity range of 0.1 to 1000 poise (10 mPa.s to 100,000 mPa.s), and preferably 0.2 poise to 100 poise (20 mPa.s to 10,000 mPa.s) and Hori does not suggest viscosities greater than 100,000 mPa.s. That none of the prior art applied to support Hori discloses viscosities greater than 100,000 mPa.s. Therefore, applicant contends that the rejection should be withdrawn since Hori alone or in combination with the supporting references does not suggest a viscosity of 300,000 mPa.s or more.

b) Applicant further argues that with respect the claim 29, Hori's disclosure of polyvinyl alcohol is insufficient to support itaconic acid, maleic acid or sulfonic acid modified polyvinyl alcohol.

c) Claims 35 and 36 exclude a heating step and therefore, Hori does not render obvious these claims.

Response:

Regarding b), these claims are not included in the art rejection because applicant the claims 29 and new claims 37-39 fail to describe what itaconic acid, sulfonic acid and maleic acid modified polyvinyl alcohol would be and failed to describe how to make the modified polyvinyl alcohol. The mention in paragraph 39 of the instant specification, of itaconic acid, sulfonic acid

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and maleic acid modified polyvinyl alcohol without providing what the modified polyvinyl alcohol may be represents an invitation to experiment with varied experimental conditions and concentrations of itaconic acid, sulfonic acid and maleic acid and polyvinyl alcohol and to determine each of the products that would be formed.

Regarding c), claim 36 specifically recites in line 4 that the composition is warmed and a warming or heating step is not excluded in claim 36. The warming step of claim 36 reads on the heating step of Hori. The absence of heating in claim 35 introduces new matter into the specification as filed. Secondly, since claim 36 includes a warming step, it flows that excluding or including a heat step may not provide unexpected results to the hair removal process. The specification does not provide a showing lending unusual effects from heating/warming. Furthermore, most chemical reactions are endothermic or exothermic, it would flow that there would be some exchange of heat and as such, is applicant wants to exclude a heat/warm step, applicant must specifically exclude heating/warming.

Regarding a), the Hori discloses that the viscosity of the gel can be increased by 10,000 and 500 fold. Therefore, Hori suggests increasing the viscosity of the gel. Secondly, applicant's specification does not provide data showing that a viscosity of 300,000 mPa.s or more provides unexpected/unusual results to the depilatory gel. The Hori gel is effective in removing hair and both the claimed gel and the disclosed gels are in the form of sheets. It is examiner's position, a gel having a single viscosity is not contemplated and therefore, a gel having a single viscosity point of 300,000 mPa.s is not inventive over the gel of the prior art in the absence of factual evidence and in the face of a disclosure that contemplates gel having range of viscosities.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594.

The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

